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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,264	04/24/2001	Ranjani V. Parthasarathy	56286USA4A.003	5359

32692 7590 04.08/2003

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841264

Applicant(s)

Parthasarathy et al

Examiner

Hoff

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12/26/02 & 1/15/03.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-45 is/are pending in the application.
- ☐ Of the above claim(s) 25-45 is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1-27 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5+4 (filed 12/24/02 & 1/15/03)
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The amendment of 1/15/03 amended the specification and claims 12, 31, 38 and 41. Amended claims, 31, 38 and 41 are nonelected claims.

The remarks in the amendment state that an Information Disclosure Statement (IDS) was filed 2/28/02, and a copy of form PTO-1449 submitted
5 with the IDS has been provided. However, there is no record in this application of an IDS filed on 2/28/03. The IDS and references did not reach the file. For the IDS to be considered, the IDS will need to be resubmitted along with copies of documents listed on form PTO-1449. Applicants will need to pay the fee of \$180.00 unless a copy of a stamped
10 receipt from the Patent Office listing the IDS containing the date of 2/28/02 can be provided as evidence that the IDS was filed 2/28/02. Also, a copy of the cover letter and attached PTO-1449 accompanying the IDS when filed 2/28/02 must be provided with the stamped receipt.

Claims 25-45 are withdrawn from further consideration pursuant to 37
15 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 3 filed 7/22/02.

Applicants request reconsideration and withdrawal of the restriction requirement, and request rejoinder of the nonelected claims. However, in
20 the election of 7/22/02, applicants stated that the election is made without traverse, and requested that claims 24-25 be withdrawn from examination without prejudice. Applicants may not elect without traverse and then subsequently traverse the requirement.

Claims examined on the merits are 1-24.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 5-16, 20 and 23 are rejected under 35 U.S.C. 103(a) as
5 being unpatentable over Park et al (5,861,251) in view of Shultz et al
(6,242,235 B1) and Hayes et al (5,721,123) for reasons set forth in the
previous office action of 10/15/02.

The claims are drawn to a composition containing an enzyme which can
be a polymerase, a dye that inactivates the enzyme and a nonionic or
10 zwitterionic surfactant that inhibits inactivation of the enzyme by the
dye. Also claimed is a method of stabilizing an enzyme by combining the
surfactant with the enzyme and dye.

Park et al disclose a PCR reagent mixture containing a polymerase, a
dye and a nonionic surfactant (col 3, lines 1-30). The nonionic
15 surfactant improves reactivity of the PCR mixture.

Shultz et al disclose stabilizing polymerases with nonionic
surfactants (col 6, lines 40-43).

Hayes et al disclose using heat absorptive dyes for enhancing the
heating effect of electromagnetic radiation when carrying out the PCR
20 process (col 3, lines 7-36).

It would have been obvious to include in the PCR reagent mixture of
Park et al a nonionic surfactant to obtain its function to improve
reactivity as taught by Park et al and to obtain its function to
stabilize the polymerase as taught by Shultz et al. It would have been
25 further obvious to include in the reagent mixture a heat absorptive dye

to obtain its function of enhancing the heating effect of electromagnetic radiation as taught by Hayes et al. The dye of Park et al and/or the heat absorptive dye of Hayes et al would have inherently reduced polymerase activity in the absence of the surfactant. Selecting another
5 surfactant such as a zwitterionic surfactant that functions to stabilize polymerase similar to a nonionic surfactant would have merely required limited routine experimentation and been obvious.

Response to Arguments

Applicants urge that the references do not teach that the dye
10 inactivates the enzyme in the absence of the surfactant. However, as stated in the rejection, the dye of Park et al and/or the heat absorptive dye of Hayes et al would have inherently reduced polymerase activity in the absence of the surfactant.

Applicants urge that Park et al do not explicitly disclose a
15 combination of dye and surfactant by not disclosing specific examples where the dye and surfactant are combined. However, Park et al clearly teach that the dye can be used in the presence/absence of the stabilizer which can be the surfactant (col 3, lines 30-35). Therefore, it is clearly obvious from the teachings of Park et al to use the dye and
20 surfactant together since Park et al teach functions of the dye and surfactant that would have made their combination desirable when performing the PCR.

It is granted as urged by applicants that Shultz et al does not disclose a dye and Hayes et al does not disclose a surfactant. However,
25 these references are combined with the Park et al reference which

suggests the a combination of dye and surfactant. The references are applied together and must be considered in combination as a whole rather than each alone.

It is granted as urged by applicants that inherency cannot be used
5 to establish obviousness in a 103 rejection. However, in the present case, inherency is not being used to establish obviousness. Nowhere does the rejection state that the invention is obvious because of the inherency. The rejection states that the invention is obvious for reasons other than the inherency, and the inherency results when
10 performing the obvious invention for the reasons other than the inherency.

Applicants urge that in Example 6, Park et al disclose that bromophenol blue, xylene cyanole, bromocresol red and cresol red did not decrease the level of the PCR. However, the present specification
15 discloses (paragraph bridging pages 8 and 9) that suitable dyes absorb energy at a wavelength of at least 400 nm. This would appear to include the dyes used by Park et al that are disclose to not decrease PCR level. Applicants may be using a different method for determining a decrease in enzyme activity due to the dye than used by Park et al for determining a
20 decrease in PCR level. In any event, Park et al disclose that methyl green decreased the PCR level, and the use of this dye in combination with the surfactant would have been obvious.

Claim Rejections - 35 USC § 103

Claims 2-4, 17-19, 21 and 24 are rejected under 35 U.S.C. 103(a) as
25 being unpatentable over the references as applied to claims 1, 5-16, 20

and 23 above, and further in view of Nadeau et al (5,919,630) for reasons in the previous office action.

The claims require the dye to be a near-IR dye.

Nadeau et al disclose using near-IR dyes as part of a donor/acceptor dye pair for carrying out the PCR (col 9, line 38, and col 2, line 42).

When modifying the PCR reagent mixture of Park et al as set forth above, it would have been obvious to further include in the PCR reagent mixture a near-IR dye to obtain its function in a donor/acceptor dye pair as taught by Nadeau et al.

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Response to Arguments

Applicants urge that Nadeau et al does not disclose a surfactant. However, Nadeau et al is not applied alone, and a surfactant is suggested by Park et al, as well as Shultz et al.

Double Patenting

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Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 09/841,272. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed composition and method would have been obvious from the claims of the copending application that require a composition containing an enzyme such as a polymerase, a nonionic or zwitterionic surfactant and a near-IR dye.

20

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants state that an appropriate response will be made when allowable subject matter is indicated.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension
5 of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the
10 end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing
15 date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00
20 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number
25 (703) 308-4743.

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The fax phone number is (703) 872-9306 before final rejection or
(703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this
application or proceeding should be directed to the Group receptionist
5 whose telephone number is (703) 308-0196.

10 DMN
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